Reviewer's report

Title: A nurse-delivered mental health intervention for obstetric fistula patients in Tanzania: Results of a pilot randomized controlled trial

Version: 0 Date: 06 Apr 2017

Reviewer: Alison El Ayadi

Reviewer's report:

Thank you so much for the opportunity to review this very interesting manuscript reporting the results of a pilot test of a mental health intervention for women affected by obstetric fistula in Tanzania. The manuscript is clearly written and addresses a topic of importance as more women are repaired for obstetric fistula yet the evidence base on mental health (and other reintegration assistance) is lacking. I appreciate the authors straightforward report of the limitations to the study design and sample, as well as the potential for such an intervention in larger studies. Below I have listed several comments and questions detailed below that I feel would improve this paper.

1. Page 3, line 11 - I recommend adjusting the language 'when prolonged obstructed labour is not relieved by cesarean delivery' because it does not adequately address the time component. Prolonged obstructed labor may be relieved by cesarean delivery but not before adequate tissue damage has been done to result in the development of a fistula.

2. Page 3, line 40 - The language in this sentence may be too optimistic given the varying definitions of treatment success and levels of persistent incontinence following surgery.

3. Page 4, line 35-40 - it may be helpful to describe in more detail the average number of fistula patients at any one time given the potential for cross-contamination of intervention effect due to what has been described in the randomization protocol. Furthermore, the literature on women and girls affected by fistula shows that patients often have not met others with the condition prior to accessing treatment at a hospital or camp and that the social support provided in such a context by others having undergone similar experiences is quite significant.

4. Page 5, line 38 - could you contextualize the post data collection point in the treatment process for fistula, i.e., did this occur after catheter removal and woman's experience of surgical outcome?
5. Page 6, line 16 - to be completely clear, the community health nurse was not hospital-based staff that was conducting any other clinical care with patients aside from the intervention over the course of the study?

6. Page 6, lines 18-27 - this section would be improved by inclusion of greater detail on the intervention targets.

7. Page 6, lines 26-29 - the paper would be improved by inclusion of the theory of change behind the intervention, particularly with the two follow-up points.

8. Page 6, line 33 - the surveys at time points baseline, post-surgery and 3-month follow-up were all identical?

9. Page 6, line 40 - please insert who the survey was administered by. If administered by the community health nurse, this will need to be described as a potential limitation due to social desirability bias.

10. Page 6-7, lines 56-40 - could you specify whether the alpha coefficients are representing populations similar to your patient population?

11. Page 8, line 55-56 - could you please provide rationale for adjusting by length of time with fistula and indicate whether this was modeled as a linear effect? I question whether the relationship of time with fistula and the outcomes is in fact linear in shape. I also wonder whether this value was mean centered for interpretability.

12. Page 9, lines 4-7 - I may not be adequately knowledgeable to comment on this component, but question whether the mental health scales included in the study can purport to establish meeting diagnostic criteria versus simply measuring the varied symptomatology. Perhaps this could be established earlier at the introduction of the measures? Additionally, it would be useful to establish that this was done using the baseline survey data (vs. baseline clinician assessment?).
13. Page 9, lines 4-47 - Could you please comment on the adequacy of the sample sizes used to establish the functional versus the dysfunctional distributions?

14. Page 10, lines 13-15 - Differentiating follow-up by intervention status is of interest in this section.

15. Page 10, lines 25-39 - The implication of the differential follow-up on the study findings should be included in the discussion section.

16. Page 10, line 42 - Again I wonder about the use of the term diagnostic criteria, and anticipate this comment will be resolved in response to my earlier question.

17. Page 12, lines 33-36 - I find it is difficult to put only the percentages here given the small ns - could this be updated to the style used on page 11, line 27 instead?

18. Discussion general - Please address the 73% retention rate in this section.

19. Discussion general - Please address the differing scales of the mental health measures in interpreting magnitude of intervention effect.

20. Page 14, lines 56-60 - This sentence could be expanded to include development of the intervention and based additionally on formative research with key stakeholders, in addition to psychological theory.

21. Table 1 - Distance from home to KCMC is presented in varying levels of precision across intervention vs. control group.
22. Table 1 - it would be informative to include the definition of successful surgery in a note under the table.

23. Table 3 - it would be informative to include the definitions of recovered and reliably improved/deteriorated in a note under the table.

24. Table 3 - please add the revised overall ns for the analyses of the 3-month follow-up data on the same lines as they are in the first half of the table.

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